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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,728	02/17/2006	John L. Russell Jr	IBT1.073-US	7147

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EXAMINER

GILBERT, SAMUEL G

ART UNIT	PAPER NUMBER
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3735

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/568,728	Applicant(s) RUSSELL JR ET AL.	
	Examiner Samuel G. Gilbert	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 16-41 is/are rejected.
- 7) ☒ Claim(s) 14 and 15 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/14/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5, 9-11, 13, 17, 20, 24-26 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 - in section b. the radiation is mixed with a fluid carrier but can be induced to solidify. It is unclear to the examiner if the applicant is intending to claim an implantable source with a sealed biocompatible capsule containing a fluid or a solid. For purposes of examination on the merits the examiner is taking this limitation to be directed to a product by process limitation and therefore the seed includes a solid within the capsule.

The claim must be written as a single sentence, the period at the end of paragraph "b." must be deleted.

Claim 2 - in line 2 - "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

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Claims 2, 3 and 17 - acronyms should be accompanied by the terms they represent, appropriate corrections should be made throughout the claims. What does PEEK represent.

Claim 5 - it is unclear how the claim is claiming a single connector, how does a connector with 2 connecting end make possible hexagonal patterns. If a group of connectors is being claimed the claim should be written as a kit claim.

Claim 9 - in line 2, “, if required, or a simple retaining element” is indefinite because the language makes the metes and bounds of the claim unclear. What is required by the claim?

The claim must be written as a single sentence, the period in line 4 and capital “T” should be deleted.

Claims 10, 11, 25 and 26 - depends from claim 1b rendering the scope of the claim indefinite. The claim has not been further examined on the merits because the scope of the claim is too indefinite.

Claims 13 and 28 - “the source” lacks antecedent basis.

Regarding claims 16 and 17, the phrase “such as” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 20 - it is unclear how the claim is claiming a single connector, how does a connector with 2 connecting end make possible hexagonal patterns. If a group of connectors is being claimed the claim should be written as a kit claim.

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Claim 24 - in line 2, “, if required, or a simple retaining element” is indefinite because the language makes the metes and bounds of the claim unclear. What is required by the claim?

The claim must be written as a single sentence, the period in line 4 and capital “T” should be deleted.

Claims 25 - depends from claim 1b rendering the scope of the claim indefinite. The claim has not been further examined on the merits because the scope of the claim is too indefinite.

Claim Objections

Claims 14 and 15 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims 14 and 15 have not been further treated on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-3, 12, 16-18 and 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Ziegler et al (EP 0,996,130 A1, hereinafter Ziegler).

Claims 1, 16, 31, 32 and 34 - Ziegler teaches a sealed plastic capsule -1- made from plastic, paragraph [0016], a source of radiation uniformly mixed in a polymer, paragraphs [0019], [0052], and [0059], an x-ray marker -3-, and a radioactive isotope of iodine -125. The examiner is considering the language of paragraph b to be product by process language and the end product is a solid polymeric radiation carrier. The carrier of Ziegler is a solid polymer -2-.

Claim 2 - the capsule may be formed of a polyethylene, paragraph [0016].

Claims 3, 18 and 33 - the capsule is made from phenyletheretherketone (PEEK).

Claim 17 see claims 2 and 3 above.

Claim 12 - Ziegler teaches a plastic carrier, -1-, a marker, gold surrounding the source, paragraphs [0023] and [0024]. When the gold marker is around the source it must be sufficiently transparent the curative radiation.

Claim 5, 7 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Slater et al (6,273,851, hereinafter Slater).

Claims 5 and 20 - Slater teaches a functional unit 50a through 50g to provide connecting ends and form a treatment strand.

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Claim 7 - heat is generated by the absorption of electromagnetic fields, which include radio waves, column 3 lines 61-63.

Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Good (5,342,283).

The central core or layer used with the source of Good may be used to generate heat when radio waves are applied, Column 8 lines 7-17.

Claims 8, 9, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Slater et al, (6,264,599).

Claims 8 and 23- Slater et al teaches a spacer -160- or -260- including barbs - 164- or -266-.

Claims 9 and 24- Slater et al teaches simple retaining means -164-.

Claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by Kaplan (2002/0058853).

Claim 27 - Kaplan teaches a seed as claimed as set forth in paragraph [0047], lines 7 and 8 where the seed includes only the polymer and the radioisotope.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 19, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ziegler(EP0,996,130 A1) in view of Slater (6,273,851).

Claims 4, 19 and 35 - Ziegler teaches a device as claimed but does not teach but does not teach a socket or universal joint for accommodating attaching spacers make possible linear strands and planar arrays. Slater teaches a radioactive seed including sockets and universal joints to make possible linear strands and planar arrays.

It would have been obvious to one of ordinary skill in the medical arts to provide the seed of Ziegler with the connectors taught by Slater to provide a seed easily connected to form a seed strand with desired spacing as taught by Slater.

Claim 36 - the embodiment of figures 5 and 8 show two ball joint elements.

Claims 6, 7, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slater (6,273,851) as applied to claim 5 above and further in view of Lennox (6,159,143).

Claims 6 and 21 - Slater teaches a functional unit, spacer -50a- through -50g- but does not teach an adjunctive therapy to be released by the spacer. Lennox teaches spacers -12- that include adjunctive treatment agents. The adjunctive therapeutic

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carried by the device can include chemo-therapeutic agents, hormones, hormone agonists, gene vectors, vaccines, and monoclonal antibodies. Applicant's attention is invited to column 3 lines 58-63. It would have been obvious to provide the functional units(spacers) of Slater with any desired adjunctive therapy agents as set forth in Lennox to provide a spacer providing additional therapeutic benefits as set forth in Lennox.

Claims 7 and 22 - radio waves are electromagnetic waves.

Claims 13, 28, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ziegler(EP0,996,130 A1) in view of Lawrence (3,351,049).

Ziegler teaches a device as claimed but does not teach the use of Pd-103. Lawrence teaches the use of Pd-103 or I-125 depending on the desired half life of the implanted radioisotope. It would have been obvious to one of ordinary skill in the medical arts to use either Pd-103 or I-125 depending on the desired half life as taught by Lawrence as an ordinary design expedient to one of ordinary skill in the medical arts. Further, the examiner is taking official notice that modifying the transmission of the carrier is old and well known in the medical arts to provide the desired transmission. It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made to adjust the transmission as claimed to any desired level as an ordinary design expedient to one of ordinary skill in the medical arts.

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Claims 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ziegler(EP0,996,130 A1).

The example 2, column 10 teaches a method as claimed but form a ceramic carrier, example 1 sets forth using a polymer. It would have been obvious to one of ordinary skill in the medical arts to use the method set forth in example to use injection molding with the polymer of example 2 as a substitute method for forming the seed as set forth by Ziegler depending on the desired manufacturing method. The selection of the particular manufacturing method from a plurality of known manufacturing methods would be within the skill of one of ordinary skill in the medical arts. Such a combination would produce an expected result with a high expectancy of success because both methods are known in the arts as set forth by Ziegler.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel G. Gilbert/
Primary Examiner, Art Unit 3735